



Clinical Trials Outcomes for Opioid Use Disorders (CTO/OD)

November 29, 2018, White Oak Campus of FDA

This Scoping Meeting is focused upon examining opioid use disorder clinical trial outcome measures, with a particular focus on craving and whether ACTION should undertake efforts to develop improved craving outcome measures

The goals of this meeting are to:

1. review craving as an outcome as it relates to OUD;
2. identify if there are gaps in the literature as it relates to craving outcome measures;
3. if gaps exist, identify potential secondary analyses of existing data that could address these gaps;
4. discuss the potential utility of the concept of craving as an outcome measure in OUD treatment trials; and, and,
5. determine whether there is utility and sufficient need for ACTION to work toward developing and qualifying a craving OUD outcome measure.

CTO/OD Meeting Agenda

- 0845 – 0900 Introductions, overview to the day and goals of the meeting (Eric Strain)
- 0900 – 0910 Overview of current NIDA perspectives on clinical trial endpoints and craving as an outcome measure in OUD trials (Tanya Ramey)
- 0910 – 0920 Overview of current FDA perspectives on craving as an outcome measure in OUD trials (Celia Winchell)
- 0920 – 1015 Craving concepts, measures, and findings, especially with respect to OUD (Annie Kleykamp)
- 1015 – 1030 Break
- 1030 – 1200 Discussion
- 1200 – 1300 Lunch break
- 1300 – 1400 Discussion